PACKAGED BAG SYSTEM WITH IDENTIFICATION TAGS

PRIORITY CLAIM

The present invention claims priority under 35 U.S.C. §119(d) to French Patent Application Serial No. 03/02033, filed February 19, 2003.

FIELD OF THE INVENTION

The invention concerns an assembly including a package and a system of bags for collecting a biological fluid as well as a method of manufacturing such an assembly. For reasons of asepsis, the bag system is normally confined in a sterile fashion in the package at the time of manufacture, the package being arranged so as to be opened prior to the use of the system.

BACKGROUND

The invention may be used when a biological fluid, typically whole blood, is collected from the donor in a collecting bag. To do this, the bag system includes, in closed circuit, a device for drawing the blood which is in fluid communication with at least one blood collecting bag. In addition, the system includes a device for sampling the blood which is intended to receive some of the blood taken off, the device including at least one sampling receptacle which is associated dissociably with the system.

The use of such a sampling device makes it possible to obtain, in each receptacle, a sample of blood, the receptacles then being able to be dissociated from the system in order to analyse the samples, in particular in order to carry out serology, virology and a cell count or hematocrit.

In particular, the bag system can be used by drawing the first millilitres of blood in the sampling device, which has a certain number of advantages. Firstly, this reduces the risk of contamination stemming from the presence of bacteria or other foreign substances on the skin of the donor because the first millilitres of blood collected, to which this contamination relates, are sent into the sampling device rather than into the collecting bag. Secondly, this makes it possible to produce the samples before the bag is completely filled and consequently not to waste any time. Finally, at the time the blood is collected the loss of the volume of blood for the donor is compensated for by the addition of plasma, causing the haematocrit reading of the blood to be analysed to be lower if the sampling device is filled after the collecting bag. Consequently the count would be inaccurate.

One problem which is posed by such a system is that of

the traceability of the samples of blood contained in the receptacles. Because the purpose of the tests carried out on the samples is to know the characteristics of the blood collected, it is essential to be able to know the source of the samples. Otherwise, incorrect information may be associated with blood contained in a collecting bag, which can have serious consequences when the blood is transfused to a patient.

In current practice, the resolution of this problem falls upon the user of the bag system, who must identify, for example by means of labels, the sampling receptacles which are used to sample the blood collected in each bag system. To this end, the user must place a label on the collecting bag and on each receptacle, the labels containing information making it possible to know the source of the sample. In particular, these labels contain common information which make it possible to link the sampling receptacles to the collecting bag containing the sampled blood.

This practice is not satisfactory because it leaves room for a handling error on the part of the user, an error which is all the more probable when the user is handling a large number of bag systems.

SUMMARY

The invention includes a bag system with which at least one sampling receptacle is associated dissociably. An identification tag is disposed, prior to the packaging of the bag system, on each receptacle and on the collecting bag. The identification tag includes information for unequivocally establishing that the receptacle or receptacles and the sampling bag come from the same bag system.

By integrating the identification tag at the time of manufacture of the packaged bag system, the user merely has to open the package in order to use the bag system, without worrying about the traceability of the samples obtained.

To this end, and according to a first aspect, the invention concerns an assembly including a package and a bag system for collecting a biological fluid, in particular blood. The said system may be confined in a sterile fashion in the package, which is arranged so as to be able to be opened prior to the use of the system. The system may include a fluid collection device which is in fluid communication with at least one fluid collecting bag, and a device for sampling the fluid to be collected which includes at least one sampling receptacle associated dissociably with the system. The collecting bag and the sampling receptacles are each provided with an identification tag which includes information making it possible, after dissociation of the receptacle from the bag system, to unequivocally establish that the sampling receptacle and the collecting bag come from the same bag system.

According to a second aspect, the invention concerns a method of manufacturing such an assembly, the method including, prior to the packaging of the bag system, providing the collecting bag and each receptacle with an

identification tag which includes information making it possible, after dissociation of the receptacle from the bag system, to unequivocally establish that the sampling receptacle and the collecting bag come from the same bag system.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will emerge during the following description, given with reference to the accompanying drawings, in which:

FIGURE 1A depicts schematically a bag system for collecting blood which includes a sampling device according to a first embodiment;

FIGURE 1B depicts schematically a bag system for collecting the blood and separating the blood components which includes a sampling device according to a second embodiment;

FIGURE 2 depicts schematically the transfer portion of the sampling device depicted in FIGURE 1A;

FIGURES 3A and 3B depict schematically the transfer device of FIGURE 2 in which a sampling receptacle is disposed respectively in a position at a distance and in a transfer position; FIGURE 3C is a representation similar to FIGURE 3B showing a variant embodiment of the transfer device;

FIGURE 4 depicts schematically a bag system for collecting the blood which includes a sampling device provided with several transfer portion according to FIGURE 2;

FIGURES 5A to 5E depict schematically the transfer portion of the sampling device of FIGURE 2, respectively in front view, in perspective, in profile, in plan view and in transverse section, the sampling receptacles being in the standby position;

FIGURES 6A and 6B depict schematically the transfer device of FIGURE 5 according to a variant embodiment, respectively in front view and profile, the receptacles being in the standby position; FIGURE 6C is a view similar to FIGURE 6B in which a receptacle is in the transfer

position;

FIGURE 7 depicts a bag system for collecting the blood which includes a sampling device according to a third embodiment;

FIGURES 8A and 8B depict schematically an assembly including a package in which a bag system respectively according to FIGURES 4 and 1B is confined in a sterile fashion.

DETAILED DESCRIPTION

Figures 1A, 1B and 7 depict bag system 1 including a device for collecting the a biological fluid from a donor and at least one collecting bag 2 intended to receive the fluid collected. In a particular embodiment, the fluid may be blood.

The collection device may consist in particular of needle 3 allowing access to the vein of the donor and cap 4 protecting needle 3. In addition, needle protector 5 may be placed slidably on first tube 6. First tube 6 provides fluid communication between collecting bag and the collection device.

Bag system 1 also includes a sampling device, which is in fluid communication with collecting bag 2 by way of first tube 6 and second tube 7, which are connected at first connector 8 by a three-way junction.

In the embodiments depicted, the sampling device includes sampling bag 9 which is connected to the downstream end of second tube 7. The terms downstream and upstream are defined with respect to the direction of circulation of the blood, from the collection device to the bags and the sampling device.

The sampling device also includes a transfer device 10 for transferring the fluid which is in fluid communication with collecting bag 2 by way of first tube 6 and second tube 7, and possibly third tube 11 connected to second tube 7 at second connector 12 in the form of a three-way junction.

As depicted in FIGURE 2, transfer device 10 includes hollow guide 13, open at front part 14 to allow the introduction of sampling receptacle 15, and hollow needle 16 passing through rear part 17 of guide 13, so that the downstream part of needle 16 extends inside guide 13 and an upstream part of needle 16 extends outside guide 13. The

downstream segment of hollow needle 16 is enclosed in elastic sheath 18. The upstream segment of hollow needle 16 enables the transfer device to be connected with bag system 1. A fluid communication device or tube is then connected to the upstream segment.

First clamp 19 and second clamp 20 can be situated respectively on first tube 6, downstream of connector 8, and on second tube 7. Clamps 19 and 20 make it possible to orient the flow of fluid collected , either to sampling bag 9, where first clamp 19 is closed while second clamp 20 is open, or to collecting bag 2, where second clamp 20 is closed while first clamp 19 is open.

Sampling receptacle 15 is filled with the collected blood contained in sampling bag 9 when receptacle 15 is placed in the transfer position, namely when the downstream end of needle 16 is in fluid communication with the inside of receptacle 15, by perforation of closure element 21 of receptacle 15.

Circuit openers can be provided within bag system 1. In particular circuit opener 22 may be situated on second tube 7 close to first connector 8.

As depicted in FIGURE 1B, in order to perform steps of filtration and separation as well as the removal of leukocytes with regard to the various constituents of the blood, collecting bag 2 may be in fluid communication, by way of fourth tube 23, with satellite bags 24a-c. Leukoreduction filter 25 is situated between collecting bag 2 and satellite bag 24a. Satellite bag 24a may be in fluid communication with one or more other satellite bags. For example satellite bag 24a may be in fluid communication with two other satellite bags 24b, c. Clamp 26 may be provided on fourth tube 23 between collecting bag 2 and leukoreduction filter 25. According to one embodiment,

satellite bags 24a-c may be provided with identification tag 35.

According to a first embodiment, transfer device 10 is provided with a device for associating sampling receptacle 15, as depicted in FIGURE 2. The association device includes first 27 and second 28 set of projections distributed longitudinally on the internal surface of guide 13, respectively close to needle 16 of the guide and close to front part 14 of guide 13. The projections are arranged so as to be deformable when sliding receptacle 15 inside guide 13 so as to allow a reversible association of receptacle 15 inside guide 13. The projections allow a sliding of receptacle 15 inside guide 13 between a standby position (FIGURE 3A) at a distance from needle 16 and the transfer position (FIGURE 3B).

As depicted in FIGURES 2, 3A and 3B, the projections are flexible, in particular elastic, and are reversibly deformable from a position inclined forwards towards a position inclined towards the rear by contact of receptacle 15 when it slides inside guide 13 in the front to rear direction. When receptacle 15 is removed from guide 13, the projections incline from rear to front so that the receptacle is not dissociated from its closure element 21. In the embodiment depicted, sampling receptacle 15 includes closure element 21 whose diameter is greater than that of the body of receptacle 15 and it is during the passage of closure element 21 that the projections incline in one direction or the other.

According to a variant depicted in FIGURE 3C the projections in first set 27 situated close to needle 16 are breakable under the effect of the sliding of receptacle 15 placed in the transfer position. The perforation of closure element 21 is thus visible and the user can check that the

perforation did not take place prior to the taking of samples.

As depicted in FIGURE 4, several transfer devices 10, in each of which a sampling receptacle 15 is associated dissociably, may be connected to bag system 1 by way of second tube 7 or third tube 11, connected to second tube 7 by second connector 12. Dissociably associating several receptacles 15 with several transfer devices 10 has advantages, firstly a saving in time for the person responsible for the collecting because he or she does not have to put receptacle 15 in place in transfer device 10 and secondly a reduction in the risk of error in traceability of the donations, because this makes it possible to fix labels prior to the taking of samples, in particular at the time of manufacture.

According to a second embodiment, the association device is arranged so as to be able to support several receptacles 15 at a distance from guide 13 in a standby position and their sequential guiding in guide 13, as depicted in FIGURES 1B and 5A to 5E.

The association device and the transfer device 10 may be associated by clipping or welding or can be moulded in one and the same piece.

The association device may include housing 29 associated with guide 13. Housing 29 is provided with skirt 30 in which closure element 21 of receptacles 15 is introduced to allow longitudinal sliding of receptacles 15 in housing 29 towards guide 13. The internal wall of skirt 30 is provided with projection 31 intended, by interaction with closure elements 21, to prevent the transverse withdrawal of receptacles 15 from housing 29.

Skirt 30 includes an open end disposed opposite a scallop formed in the guide, and an opposite closed end. In

the other axis, a first open end is disposed opposite another end which is open so that the body of receptacle or receptacles 15 extends beyond housing 29.

At the time of manufacture, sampling receptacles 15 are introduced into guide 13 through its open front part 14 so that closure element 21 is situated level with groove 32 in housing 29 so that it can be slid therein.

Cap 33 is then placed on guide 13, making it possible to hold receptacles 15 in housing 29 until samples are taken by the user of system 1.

The housing can be of variable size so as to contain from two to ten receptacles 15. The number of receptacles 15 used varies according to the legislation, in France in particular five receptacles 15 are used for carrying out normal analyses.

When samples are taken, the person responsible for the sampling removes cap 33 from guide 13, makes receptacles 15 slide as far as guide 13, and then introduces them so that, by perforation of closure element 21 of receptacle 15, the downstream end of needle 16 is in fluid communication with the inside of receptacle 15. After receptacle 15 has been filled, the user withdraws it from guide 13. In one example embodiment, cap 33 may be provided with a tamper-evident element, such as a tongue which is broken on first opening, so as to be able to identify the first manipulation of cap 33.

According to a variant, depicted in FIGURES 6A to 6C, transfer device 10 can slide on the association device, so that it can be placed level with each receptacle 15. When transfer device 10 is placed level with receptacle 15, the user may then move the transfer device 10 transversely so that closure element 21 is perforated by needle 16. So that transfer device 10 may slide on the association device, two

opposite scallops are then formed in guide 13.

As depicted in FIGURE 1B, transfer device 10 associating several sampling receptacles 15 may be connected to bag system 1 by way of second tube 7 and possibly third tube 11.

According to a third embodiment, depicted in FIGURE 7, the sampling receptacle or receptacles may be flexible, preformed and connected to a tube of the bag system, in particular to second tube 7.

The sampling receptacle or receptacles 15 are filled, simultaneously or successively, with the collected blood contained in sampling bag 9.

Filling takes place by mechanical pressure on sampling receptacle 15, the air contained in preformed receptacle 15 is driven into sampling bag 9, while the blood contained in bag 9 is driven into receptacle 15.

After samples are collected, sampling receptacle 15 is hermetically welded and detached from bag system 1.

A septum 34 may be provided on the end of receptacle 15 opposite to the end where the welding is carried out. In this way, after welding, one or more sampling receptacles 15 compatible with automatic analysis controllers are obtained. In order to perform a certain number of analyses, receptacle 15 may then be placed in a receptacle of the automatic controller, and a needle of the automatic controller pierces septum 34.

With known bag systems for collecting blood, the person responsible for the collecting must, by way of some mark, identify collecting bag 2 and sampling receptacle or receptacles 15 corresponding to one and the same donation.

According to the invention, the possibility of error in traceability of these donations is considerably reduced because, as depicted in FIGURES 8A and 8B, sampling

receptacle or receptacles 15 and collecting bag 2 are dissociably associated at the time of manufacture. In addition, at the time of manufacture, collecting bag 2 and sampling receptacle or receptacles 15, as well as any satellite bags 24a-c, are each provided with an identification tag 35, for example a self-adhesive bar code label, which includes information making it possible, after dissociation of the receptacles from bag system 1, to unequivocally establish that sampling receptacle 15 and collecting bag 2, as well as any satellite bags 24a-c, come from the same bag system 1. Bag system 1 according to the invention may be packaged in flexible transparent package 36. Bag system 1 and package 36 thus form an assembly.

The method of manufacturing such an assembly makes provision, prior to the packaging of bag system 1, for providing collecting bag 2 and each receptacle 15 with an identification tag which includes information making it possible, after dissociation of the receptacle from bag system 1, to unequivocally establish that sampling receptacle 15 and collecting bag 2 come from the same bag system 1. In an example embodiment where label 35 is provided with a bar code, the bar code may be printed on label 35 subsequent to its placement.

According to a first embodiment, the method includes disposing sterilised bag system 1 in package 36 and then may include pasteurising the whole.

According to a second embodiment, the method includes disposing bag system 1 in package 36 and then sterilising the whole.

According to a third embodiment, the method includes sterilising the bag system without receptacles 15, associating receptacles 15 with the bag system, packaging the system and then possibly pasteurising the whole. This

embodiment is particularly adapted to the case where sampling receptacles 15 contain reagents sensitive to the sterilisation step. Moreover, closure elements 21 for sampling receptacles 15 may also be sensitive to the sterilisation step.